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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,434	01/31/2006	Toshiaki Iio	28951.1171	5074

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EXAMINER	
DANEGA, RENEE A	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,434	IIO ET AL.	
	Examiner	Art Unit	
	Renee Danega	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 32-43 in the reply filed on 10/15/08 is acknowledged. The traversal is on the ground(s) that the search would not be burdensome. This is not found persuasive because after conducting a search on the original claims 1-31 as well as amended claims 1-31, there were no results containing a puncture disposal instrument as claimed in claims 32-43. Additional searching is required.

The requirement is still deemed proper and is therefore made FINAL.

DETAILED ACTION

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-7, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rouviere (FR 2797579) in view of Grunert (US 3030959) and Kolomeir (US 3708235).

- Regarding claim 1, Rouviere teaches a puncture instrument (A) which houses a plurality of puncture needles (F) for puncturing the surface of a biologic body and is able to perform puncture operations continuously in which the needles are connected in series (1,2, 3) in the axis direction of

the puncture instrument (Figures 6, 9). Rouviere further teaches the instrument able to be refilled from needle columns kept in hermetically sealed packs (page 6, line 35 - page 7 line 4) but doesn't teach the column to be in a cartridge. However, Grunert teaches a puncture needle cartridge for needles kept in axial alignment for use in a puncture device (claim 1). It would have been obvious in view of Grunert to put Rouviere's needles in a cartridge in order to maintain sterility when refilling the puncture instrument. Rouviere further doesn't teach that the needles are connected in a manner that removal of a puncture needle pulls the next need to the puncture position. However, Kolomeir teaches a plurality of sharp units connected in series in such a manner that removal of a unit pulls the next unit into useable position (column 4, lines 32-57). It would have been obvious in view of Kolomeir to provide an elastic gripping portion for pulling the next needle of Rouviere and Grunert into a useable position in order to prevent accidental injury when moving the next needle forward.

- Regarding claim 2, Rouviere's needle columns are stacked in such a manner that the front end of the puncture needle is protected by a portion of another puncture needle at a rear end of the puncture needle (figure 9).
- Regarding claim 3, Rouviere teaches puncture needles comprising a needle part (Fa) and elastic deformation member (F1) wherein the front end of the puncture needle is protected by an elastic deformation member

of another puncture needle which is positioned at the rear end of the puncture needle (Figures 3, 4). As stated above, Kolomeir's puncture needle has elastic deformation members for elastically gripping the front end of the next puncture needle and pulling it forward. Rouviere doesn't teach the cartridge to hold the needles in this state. However, Grunert teaches a puncture needle cartridge for needles kept in axial alignment for use in a puncture device (claim 1). It would have been obvious in view of Grunert to put Rouviere's needles in a cartridge in order to maintain sterility when refilling the puncture instrument.

- Regarding claim 4, Rouviere doesn't teach the puncture needle cartridge stopping member. However, Grunert teaches a cylindrical needle cartridge with a puncture needle cartridge stopping member for stopping the cartridge at a pre-determined position in a case, a biasing member for moving the cartridge in one direction, and a puncture button for starting a puncture operation (column 3, lines 39-65). It would have been obvious in view of Grunert to provide biasing member and puncture button in order to control of the needles and cartridge within the puncture instrument.
- Regarding claim 5, Rouviere teaches a remaining quantity check means (J) for checking the remaining quantity of the plural puncture needles (Figure 7).

- Regarding claim 6, Rouviere teaches the remaining quantity check means to have a check window (J) on the side of the puncture instrument (Figure 7).
- Regarding claim 7, Rouviere doesn't teach a puncture needle cartridge to be detachably provided in the puncture instrument. However, Grunert teaches a puncture needle cartridge detachably provided in the puncture instrument (column 3, lines 55-65). It would have been obvious in view of Grunert to provide a detachable needle cartridge in Rouviere's device to enable sterile reloading of the puncture instrument.
- Regarding claim 26, Rouviere teaches a puncture instrument (A) which houses a plurality of puncture needles (F) for puncturing the surface of a biologic body and is able to perform puncture operations continuously in which the needles are connected in series (1,2, 3) in the axis direction of the puncture instrument (Figures 6, 9). Rouviere teaches a puncture needle replacement jig (B) which is able to remove the used puncture needle and set the puncture needle at a puncture operation start position (Figure 12). Rouviere further teaches the instrument able to be refilled from needle columns kept in hermetically sealed packs (page 6, line 35 - page 7 lines 4) but doesn't teach the column to be in a cartridge. However, Grunert teaches a puncture needle cartridge for needles kept in axial alignment for use in a puncture device (claim 1). It would have been obvious in view of Grunert to put Rouviere's needles in a cartridge in order

to maintain sterility when refilling the puncture instrument. Rouviere further doesn't teach that the needles are connected in a manner that removal of a puncture needle pulls the next need to the puncture position. However, Smith teaches a puncture instrument in which the needles are all connected and removal of a puncture needle pulls the next needle to the puncture position so that the used needle can be disposed of (column 25, lines 6-49). It would have been obvious in view of Smith to provide a connection that pulls a new needle to puncture position in Rouviere in order to allow the used needle to be disposed of.

- Regarding claim 27, Rouviere teaches the replacement jib including a return member that holds the needle after puncturing and removes it (B1) (Figure 12).
- Regarding claim 28, Rouviere teaches the puncture needle replacement jig sets the puncture needle at the start position simultaneously with the removal of the puncture needle (Figure 12).
- Regarding claim 29, Rouviere teaches the puncture needle is removed by a replacement jig after puncturing (Figure 12) as well as stopping members holding each member in a predetermined position (C, D) (Figure 5a). Rouviere doesn't teach the needles to be in a cartridge. However, Grunert teaches a puncture needle cartridge for needles kept in axial alignment for use in a puncture device (claim 1). It would have been

obvious in view of Grunert to provide a cartridge with Rouviere's stopping mechanisms in order to regulate the expulsion of the needles.

- Regarding claim 30, Rouviere teaches puncture needle retaining elastic member (D) bending within an elasticity range of the puncture needle retaining elastic member due to fitting the elastic member to the replacement jig (E) (Figure 15) to dissolve the hold.
- Regarding claim 31, Rouviere teaches a remaining quantity check means (J, K, F) (Figure 7).

4. Claims 8-17 and 21-22, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunert et al. (US 3030959) in view of Kolomeir (US 3708235).

- Regarding claim 8, Grunert teaches a puncture needle cartridge which contains a plurality of puncture needles for puncturing the surface of a biologic body and is housed in a puncture instrument that is able to perform puncture operations continuously with the puncture needles in series in an axis direction of the puncture instrument (column 3, lines 39-72) (Figure 1). Grunert doesn't teach the needles to be connected in series. However, Kolomeir teaches a plurality of sharp units connected in series in such a manner that removal of a unit pulls the next unit into useable position (column 4, lines 32-57) (Figures 3, 5). It would have been obvious in view of Kolomeir to provide an elastic gripping portion for pulling the next needle of Grunert into a useable position in order to prevent accidental injury when moving the next needle forward.

- Regarding claim 9, Grunert doesn't teach front ends of the needles fitting in another needle. However, Kolomeir teaches the sharp units fitting into each other as stated above.
- Regarding claim 11, Grunert teaches the needle cartridge to further include puncture needle stopping member for holding the respective puncture needles at predetermined positions in the cartridge (column 3, line 65-74).
- Regarding claim 12, Grunert doesn't teach the stopping members provided at a regular interval approximately equal to the length of the puncture needle. However, Kolomeir teaches providing stopping members at the front and rear of the device to prevent sharp units from falling out (column 3, line 60 – column 4, line 32). It would have been obvious in view of Kolomeir to provide stops at both ends of the device to prevent needles from falling out of the housing.
- Regarding claim 13, Grunert doesn't teach fitting strength of the needles larger than a load applied. However, Kolomeir teaches the fitting strength strong enough to prevent the sharp unit from moving back into the casing or fall out (column 3, line 43 - column 37). It would have been obvious in view of Kolomeir to provide adequate strength between the units of Grunert to prevent a needle from accidentally falling out.

- Regarding claim 14, Grunert teaches a puncture needle retaining elastic member (9) for holding a puncture needle to prevent escape and dropout of the puncture needle from the puncture instrument body (Figure 4).
- Regarding claim 15, Grunert is silent as to whether the puncture needle retaining elastic member is part of the puncture cartridge. However, this is one of a finite number of variations (i.e. integrated with the cartridge or integrated with the instrument body) and would have been an obvious variation to one of ordinary skill in the art.
- Regarding claim 16, Grunert doesn't teach dents for retention on the puncture needles. However, Kolomeirs elastic connection uses dents (15) (Figure 3).
- Regarding claim 17, Grunert teaches providing a puncture needle cap which protects a needle part of a puncture needle that is positioned at the head of the group (26) (Figure 1).

5. Claims 19-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunert modified by Kolomeir as applied to claim 8 above, and further in view of Rouviere (FR 2797579).

- Regarding claim 19, Grunert modified by Kolomeir doesn't teach a remaining quantity check means. However, Rouviere teaches a remaining quantity check means (J, K, F) (Figure 7). It would have been obvious in view of Rouviere to provide a remaining quantity check means in Grunert

modified by Kolomeir's device in order to determine how many new needles remain for testing.

- Regarding claim 20, Rouviere's remaining quantity check means varies respective colors (K) (Figure 7).
- Regarding claim 21, Rouviere's remaining quantity check means assigns numbers (production codes) (page 18, lines 9-14) (Figure 13).
- Regarding claims 22-23, Grunert teaches a new puncture needle group capable of being loaded in the cartridge and that it is loaded in one direction (column 3, lines 55-72) (Figure 1).

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736